Alice M. Whitaker

GlaxoSmithKline

0664 5 NOV -7 A9:48

GlaxoSmithKline

November 1, 2005

Division of Dockets Management (HFA- 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Ref: Final Rule on **Bar Code Label Requirement for Human Drug Products and Biological Products**, *Federal Register*, February 26, 2004; and Draft Guidance on **Bar Code Label Requirements- Questions and Answers**, *Federal Register*, June 7, 2005.

GlaxoSmithKline supports the use of bar codes in labels. We acknowledge both the FDA's efforts and those of the PhRMA members in the preparation of the final rule and draft guidance. GSK understands that the use of bar coded labels to properly identify the product at the unit of use or unit dose level will help avoid many dispensing errors. Scanning bar codes at the time of dispensing to the patient, along with scanning the patient's wristband will ensure that the patient receives the correct dose of the right product at the right time. The effective date of the final rule was April 26, 2004.

In reviewing the final rule, we find the following in Section II.I (I. *How Will We Implement the Rule?*) " ...for drugs that are approved on or after the effective date of this rule, we would expect compliance within 60 days after the drug's approval date...for drugs approved before the effective date of this rule, we would expect compliance within 2 years after that date...A 2-year implementation period will also enable firms to exhaust existing stock. If a drug has an expiration date that exceeds 2 years, and the drug was not subject to the bar code requirement at the time it was marketed, we will allow that drug to remain on the market without a bar code. However, we recognize that we cannot preclude the possibility that some drug products may be difficult to bar code, either because of their containers, size, or other complications. Therefore, if a manufacturer, repacker, or private label distributor can demonstrate to us that, for technological reasons, it cannot comply within 2 years after the final rule's effective date, it should contact us..."

Furthermore, the response to Q7 in the draft guidance (*How is the 2 year implementation date intended to work?*) reads "A7: The 2 year implementation date is for drug products that received approval before April 26, 2004. This 2 year period is intended to provide the industry sufficient time to make the labeling changes necessary to comply with the rule by April 26, 2006. Drugs approved on or after April 26, 2004, have 60 days from their approval date to comply with the bar code rule."

2005D-0202

C 6

In reading this answer (A7), GSK is concerned that this section of the regulation may be interpreted as **all product shipped after April 26, 2006, must comply with the regulation**. If interpreted in this way, the challenge to enforce compliance with the rule will be difficult for both the industry and FDA as it could necessitate relabeling or repacking goods which have already been packaged but not yet distributed, increasing the potential for disruption of product supply. GSK proposes that the benefits of this interpretation do not outweigh the burden of conducting the repackaging and relabeling operations. Additionally, GSK understands that the FDA did not intend to create such a burden when they developed the implementation date of 2 years from the effective date of the rule (vs. the 3 years which was originally proposed). Therefore, GSK requests that the agency publish an official clarification of the terms of compliance, stating that all products **packaged** on or after April 26, 2006 must contain bar codes.

Sincerely,

Janice M. Whitaker